



CDISC Library

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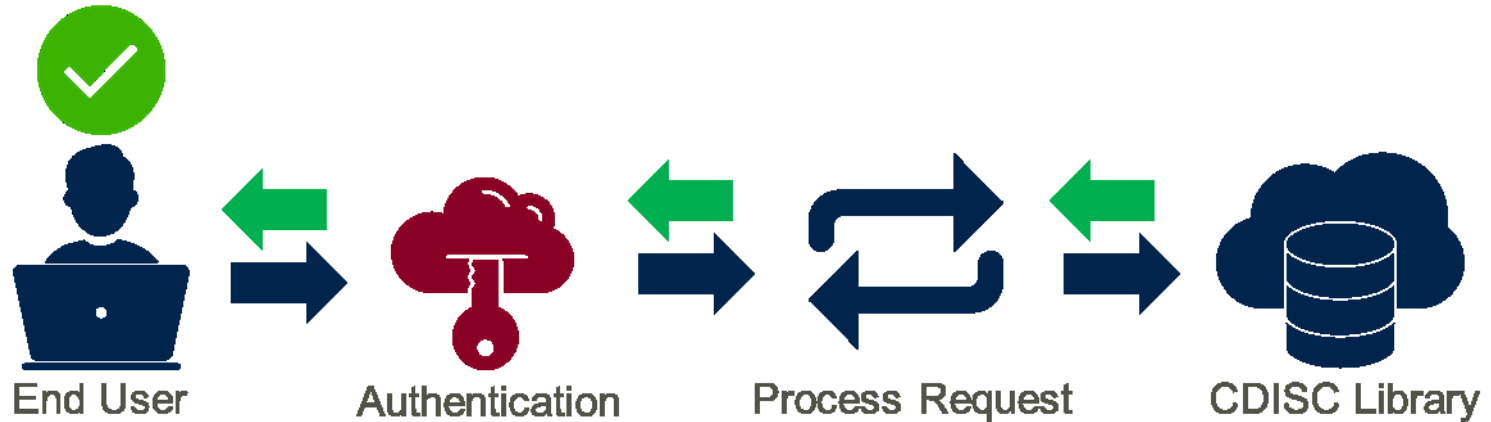


CDISC Library, an **ISO 11179** applied **Metadata Repository**, built on semantic architecture using the **Resource Description Framework (RDF)**. It uses linked data and a **REST API** to deliver CDISC standards metadata to software applications that automate standards-based processes.

CDISC Library provides access to a substantially increased number of **versioned CDISC standards** and controlled terminology packages, including new **relationships** between the standards. CDISC Library is the single, trusted, **authoritative source** of CDISC standards metadata and represents a new way of creating, maintaining, and publishing this metadata.

In non-technical terms, it means that CDISC Library will remain **flexible** and **adaptive** for the future. It will continue to provide the key metadata described to **support your organizational needs**.

Accessing API Content – Data Flow



- A note on authentication: authentication, followed by authorization
 - A user may be authenticated, but not authorized to use certain functionality
 - For example, system administration tasks



Agenda

- Activity: *What Are The Metadata?*
- Demo 1: Data Standards Browser
- Demo 2: Machine-Readable Metadata Via API
- Who Is Using CDISC Library?

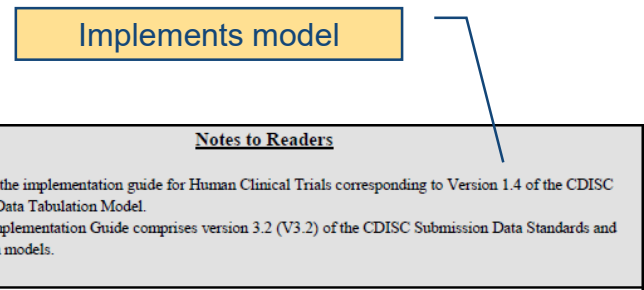
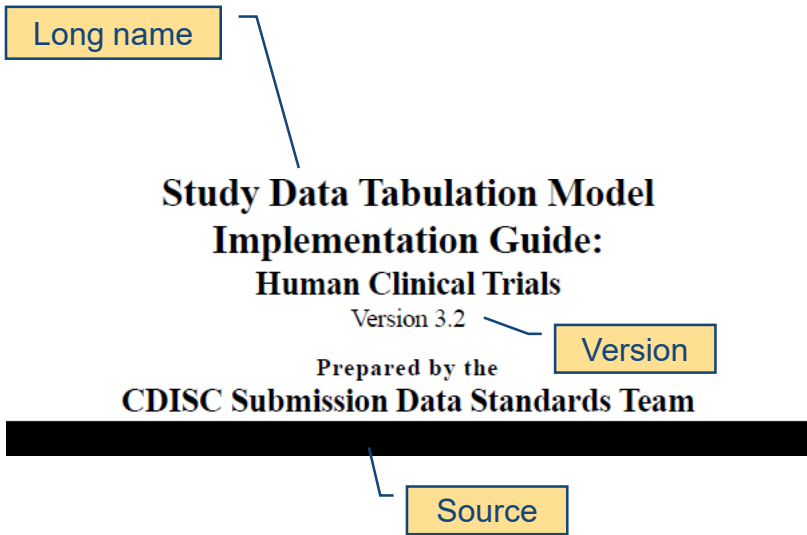
What Are The Metadata?

dm.xpt, Demographics — Version 3.2. One record per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char	CT	Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone the date requires, such as screen failures or unassigned subjects.	Exp

Annotations: Ordinal, Data Type, Short name, Long Name, Version, Structure, Purpose, Notes, Variable, Label, Format, Role, Core.

What Are The Metadata?



What Are The Metadata?

TSPARMCD	TSPARM	TSVAL (Codelist Name or Format)	Record with this Parameter	Notes
ADDON	Added on to Existing Treatments	No Yes Response	Required	
AGEMAX	Planned Maximum Age	ISO 8601	Required	If there is no maximum age, TSVALNF = PINF
AGEMIN	Planned Minimum Age	ISO 8601	Required	If there is no minimum age, populate TSVAL with POY
LENGTH	Planned Trial Length	ISO 8601	Required	
PLANSUB	Planned Number of Subjects	number	Required	
RANDOM	Trial is Randomized	No Yes Response	Required	
SEXPOP	Sex of Participants	Sex of Participants	Required	
STOPRULE	Study Stop Rules	text	Required	Protocol-specified stopping rule. If there is no stopping rule record "NONE" in this field.
TBLIND	Trial Blinding Schema	Trial Blinding Schema	Required	
TCNTRL	Control Type	Control Type	Required	
TDIGRP	Diagnosis Group	SNOMED CT	Conditionally Required	If the study population is healthy subjects (i.e., healthy subjects flag is Y), this parameter is not expected. If the healthy subject flag is N, then this parameter would contain the diagnosis/medical problem of the study population. [Validation rule; IF healthy volunteers = N then TDIGRP must be present and not null]
TINDTP	Trial Indication Type	Trial Indication Type	Conditionally Required	If study type is "INTERVENTIONAL" this parameter is required. A study in healthy volunteers may have TSVAL null and TSVALNF = NA.
TITLE	Trial Title	text	Required	Use as many rows as needed.
TPHASE	Trial Phase Classification	Trial Phase	Required	
TTYPE	Trial Type	Trial Type	Required	Use as many rows as needed.

CT

CT

Format

Data type

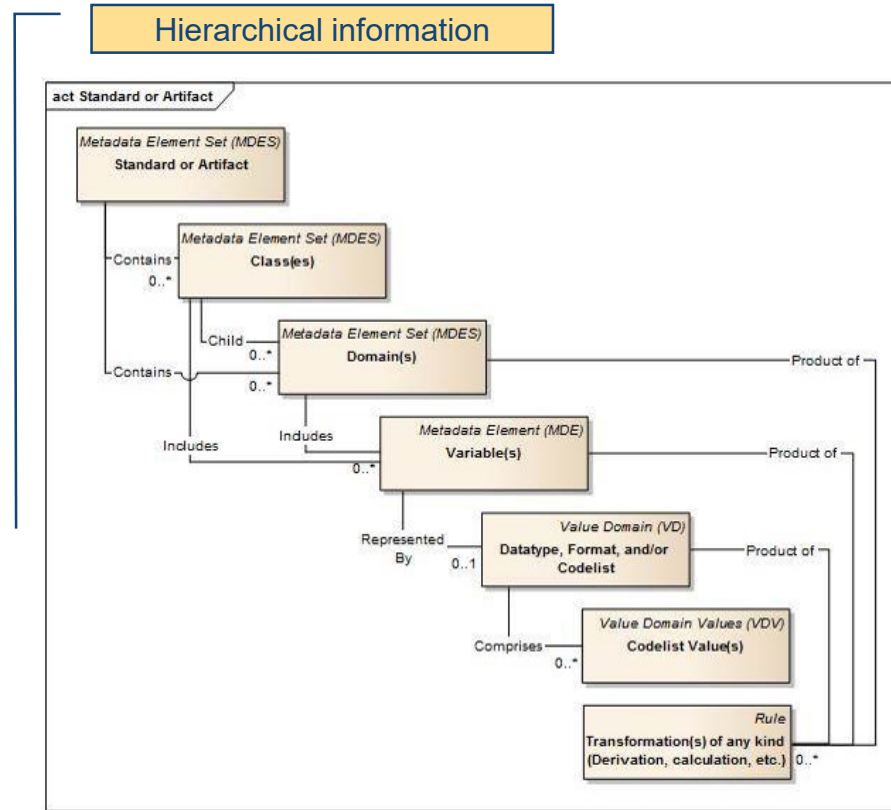
Data type

CT

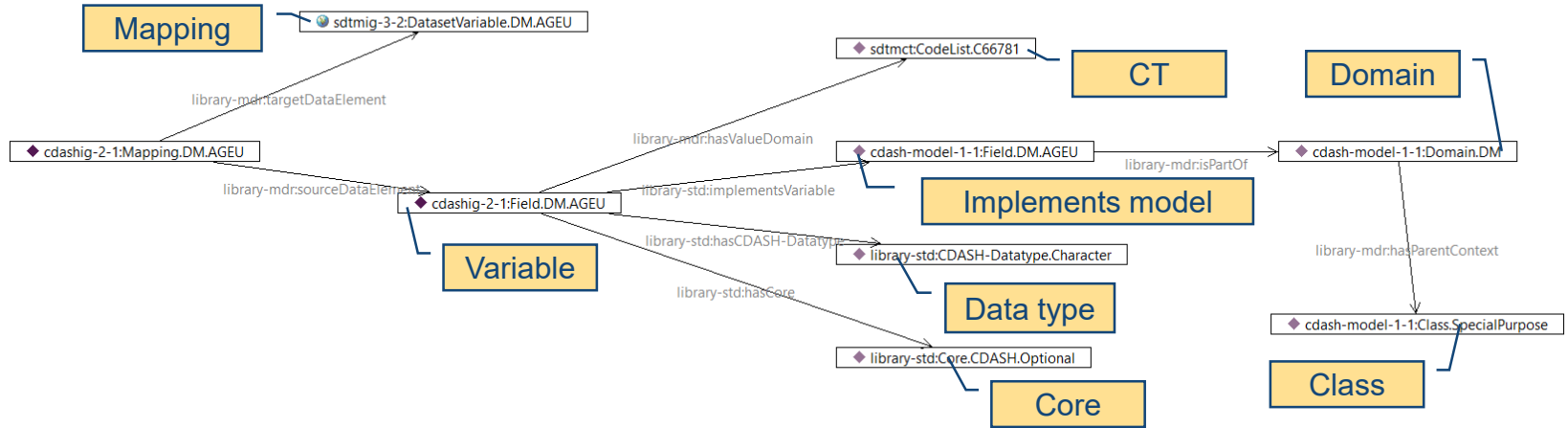
External dictionary

Data type

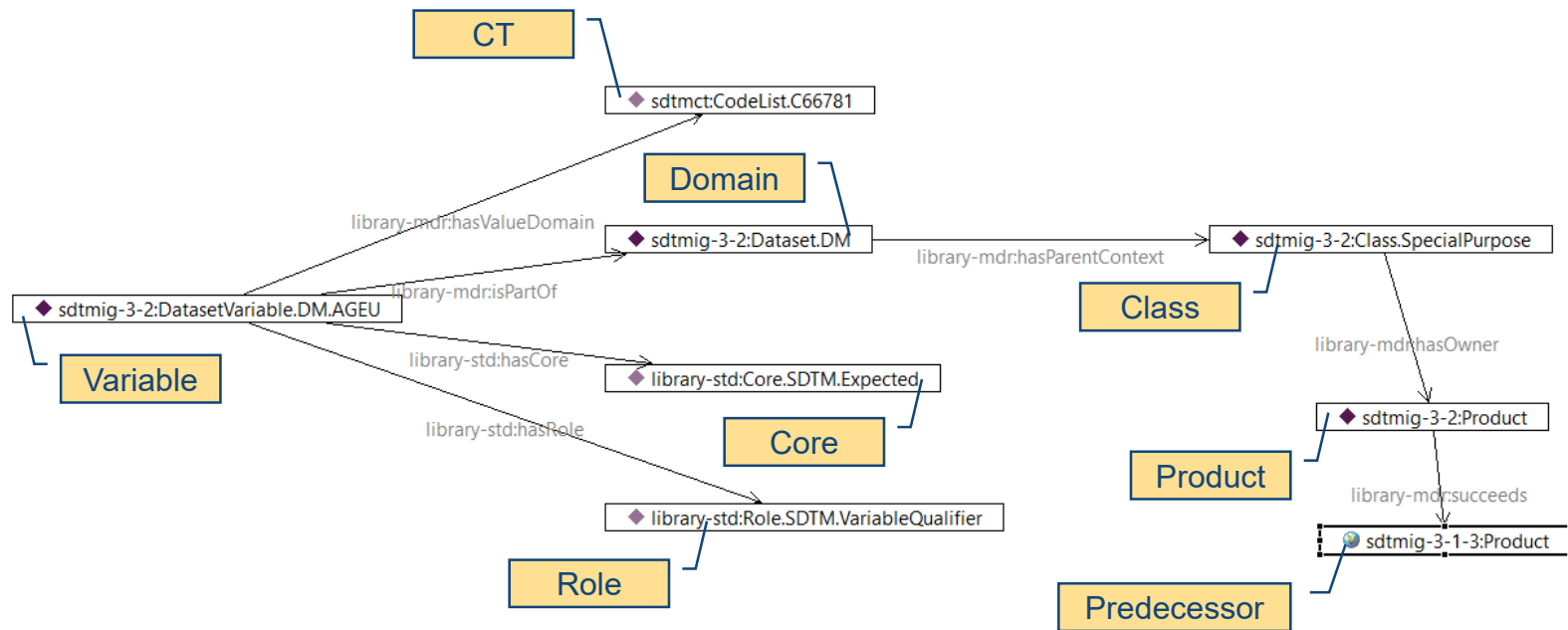
What Are The Metadata?



Metadata Relationships – CDASH

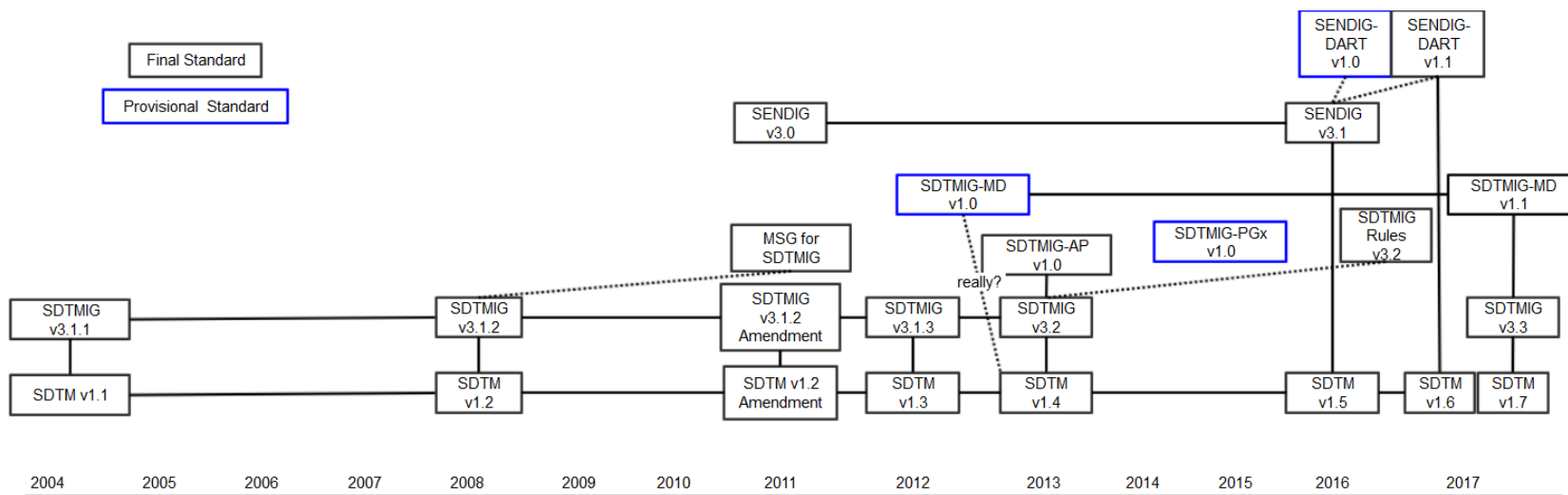


Metadata Relationships – SDTM



Product Relationships

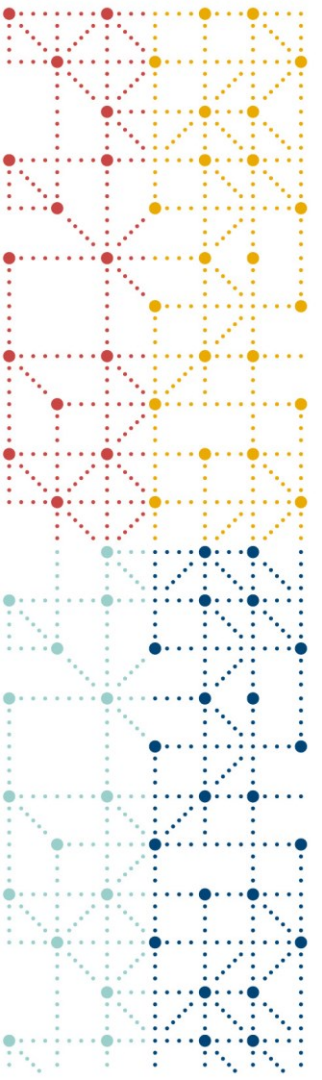
- Below is a hand-drawn graph depicting lineage of SDTM & SEND products





Takeaway

- Machine-readable
- Well-defined
- Has a schema
- Has relationships
- Has a programming interface



Demos

2017 Survey

Is your organization planning to use the SHARE API? (n=238)

- 71% Not sure
- 17% Yes
- 12% No



2017 Survey

How are you planning on using the SHARE API?

- **74% Institutional metadata repository**
- **32% Enterprise I.T. application**
- **23% Ad-Hoc programming & reporting**



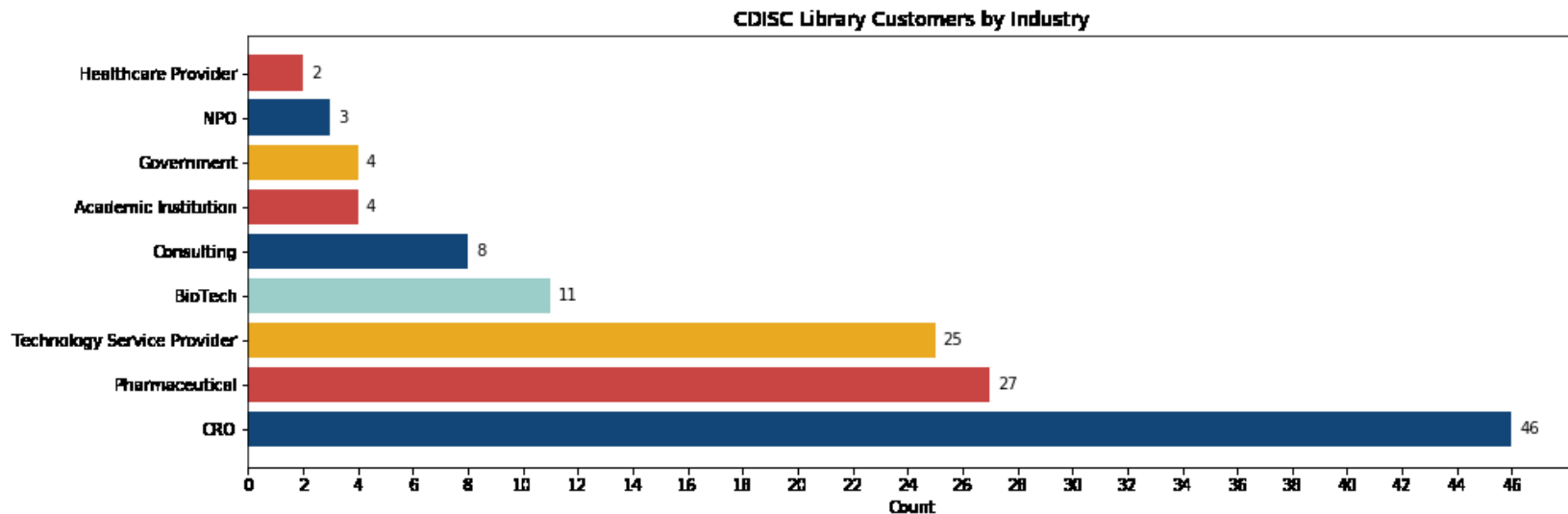
2017 Survey

Why is your organization not planning on using the SHARE API?

- **32% What is the SHARE API?**
- **25% No plans to implement an institutional metadata repository**
- **21% Concerns about cost**

Customers by Industry

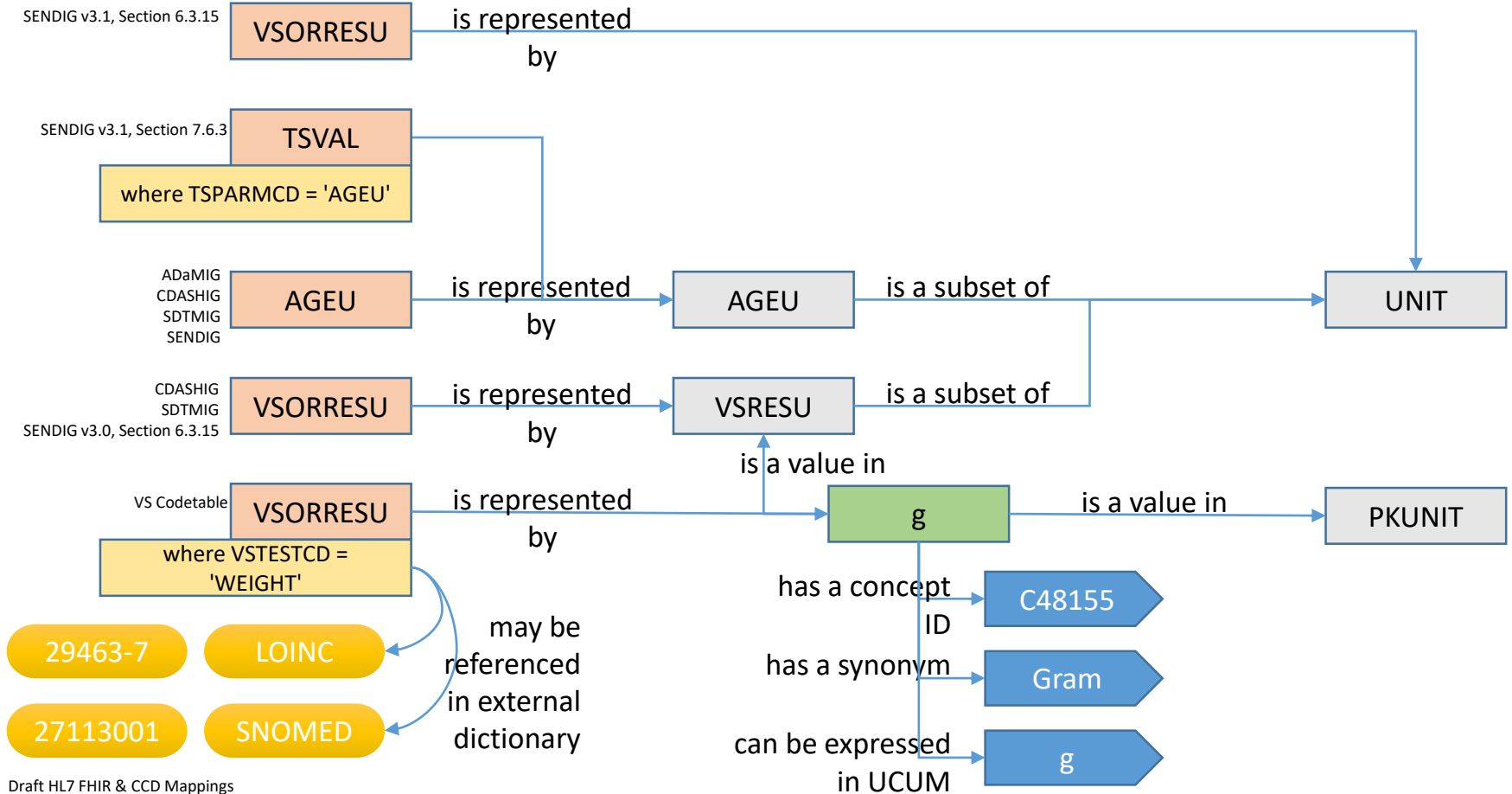
- 133 member organizations signed up for CDISC Library access



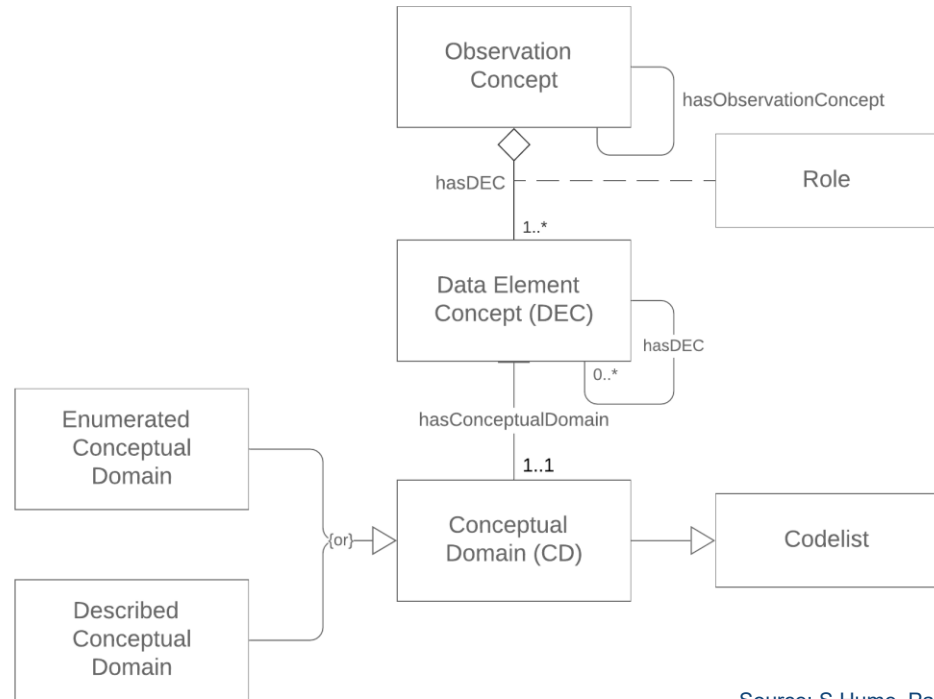
CDISC Library Content Snapshot

- **110+ Versioned Standards: CDASH, SDTM, SEND, ADaM, CT**
- **1.8 Million+ Resources**
- **8 Million+ Relationships**
- **200,000+ API queries processed to-date**
 - **Controlled Terminology: 56%**
 - **Data Tabulation (SDTM, SDTMIG, SENDIG): 32%**
 - **Data Collection (CDASH Model, CDASHIG): 10%**
 - **Data Analysis (ADaM, ADaMIG): 2%**

A SLICE OF MULTI-DIMENSIONAL INTRICACIES OF CONTROLLED TERMINOLOGY

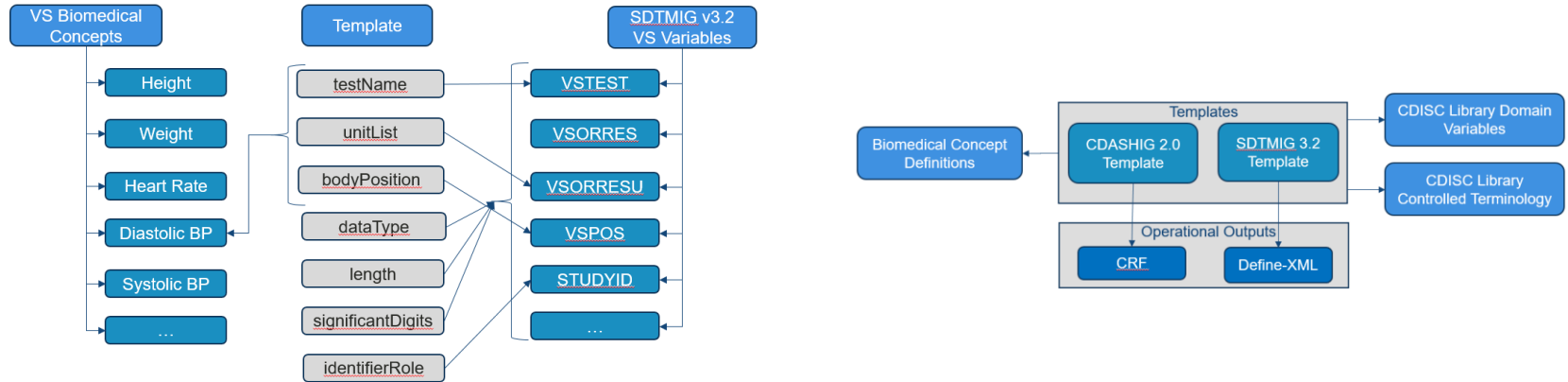


Future State: Biomedical Concept Meta-Model



Source: S Hume. Paper TT06. PHUSE US Connect 2020.

Future State: CDISC 360 Biomedical Concepts



Source: S Hume. Paper TT06. PHUSE US Connect 2020.

Access

- **CDISC Library access included in CDISC membership**
- **Volume account option available**
- **Academia intuitions**
- **Open-source developers**
- **Commercial software licenses**

Contacts & Helpful Links

- Email: achow@cdisc.org
- LinkedIn: <https://www.linkedin.com/in/achow>
- Overview: <https://www.cdisc.org/cdisc-library>
- General CDISC Library Inquiry: <https://www.cdisc.org/cdisc-library/api-account-product-inquiry>
- API Documentation: <https://www.cdisc.org/cdisc-library/api-documentation>
- Release Notes: <https://wiki.cdisc.org/display/LIBSUPRT/Release+Notes>